

REMARKS

Claims 1 and 31 have been amended. Claims 2-3 and 32-73 have been cancelled without prejudice. Subsequent to the entry of the present amendment, claims 1 and 4-31 are pending and at issue. These amendments and additions add no new matter as the claim language is fully supported by the specification and original claims.

I. Amendment to the Claims

Claims 32-73 are directed to unelected subject matter and have been canceled.

Claim 1 has been amended to incorporate the subject matter of claims 2 and 3, which have been canceled. Claim 31 has also been amended to incorporate the subject matter of claims 2 and 3, and to improve its form.

The amendments add no new matter as they are fully supported by the specification and original claims.

II. Double-patenting rejection

Claims 1-26 and 29 are rejected on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1-35 of U.S. Patent No. 6,835,717 (hereinafter, the “717 patent”) in view of Khanna et al. (Jan. 2002) *J Clinical Investigation* 109:205-211 (hereinafter, “Khanna”) and Biggar et al. (1996) *Lancet* 347:1647 (hereinafter, “Biggar”).

Terminal Disclaimers, disclaiming any patent term of the subject application that may extend beyond the term of U.S. Patent No. 6,835,717, are submitted herewith. Accordingly, it is respectfully requested that the double patenting rejection be withdrawn.

III. Rejections under 35 U.S.C. §112, First Paragraph (enablement)

Claims 1-31 are rejected under on 35 U.S.C. §112, first paragraph, for allegedly containing subject matter not described in the specification in such a way as to enable one of skill in the art to make or use the invention. Applicants respectfully traverse the rejection as it applies to the amended claims.

According to the Office Action, the specification “while being enabling for a method of *reducing* maternal to fetal transmission of microorganisms using a beta-cyclodextrin composition, does not reasonably provide enablement for a method of *preventing* maternal to fetal transmission of a microorganism using beta-cyclodextrin or any other cholesterol-sequestering agent. The specification does not [allegedly] enable reducing maternal to fetal transmission of a microorganism using a cholesterol-sequestering agent other than beta-cyclodextrin (emphasis added; page 5 of the Office Action)”.

Claim 1 has been amended to recite the following:

A method of reducing maternal to fetal transmission of a microorganism, the method comprising:

selecting a pregnant individual diagnosed as being infected with a microorganism; and administering to the birth canal of the individual a composition comprising a cholesterol-sequestering agent, wherein the agent is beta-cyclodextrin administered prior to a vaginal birth of a fetus, and wherein an amount of the agent effective to reduce or prevent maternal to fetal transmission of the microorganism remains present in the birth canal during the vaginal birth.

The amendment now recites administering a “beta-cyclodextrin”, which was the subject matter of claims 2 and 3. Claims 2 and 3 have been canceled. Claim 31 has been amended similarly but with regards to a “cesarean section birth”. The amendments are supported in the application as filed (e.g., page 6, lines 3-10; pages 9-10; and original claims 2 and 3). Further, the Office Action, on page 8, admits that the present application has shown “some working examples using certain beta-cyclodextrins”. Thus, in view of the amended claims, the present application enables one skilled in the art to make and use the claimed invention.

Accordingly, withdrawal of rejection of claims 1-31 under 35 U.S.C. §112, first paragraph is respectfully requested.

III. Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1 and 5-31 are rejected under 35 U.S.C. §112, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant traverses this rejection as it may apply to the amended claims.

According to the Office Action, the functional descriptions of chemical compounds/compositions must be coupled with a known or disclosed correlation between function and structure (page 9 of the Office Action).

Claims 1 and 31 have been amended as discussed above. Amended claims 1 and 31 correlate the structure (beta-cyclodextrin) with function ("cholesterol-sequestering agent"). Thus, one skilled in the art is apprised of the metes and bounds of the claimed invention.

Accordingly, withdrawal of rejection of claims 1 and 5-31 under 35 U.S.C. §112, second paragraph is respectfully requested.

IV. Rejections under 35 U.S.C. §103(a)

Claims 1-31 stand rejected under 35 U.S.C. §103(a) for being allegedly obvious over the '717 patent in combination with Khanna and Biggar.

To establish a *prima facie* case of obviousness, three basic criteria must be met: 1) a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference

teachings; 2) a reasonable expectation of success; and 3) the references must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP § 2143.

According to the Office Action, the '717 patent discloses methods of reducing risk of transmission of a sexually transmitted pathogen, e.g., virus transmission, using beta-cyclodextrin and a contraceptive agent. Also, according to the Office Action, although the '717 patent is deficient in teaching that beta-cyclodextrin is useful to reduce maternal to fetal transmission of a microorganism, Khanna and Biggar cure this deficiency (pages 11-12 of the Office Action).

Claims 1 and 31 have been amended as discussed above. It is submitted that none of the references "teach or suggest all the claimed limitations". First, as state by the Office Action, the '717 patent "does not explicitly state that the method is useful in reducing maternal to fetal transmission of a microorganism" (page 11). This deficiency is not cured by the combination of Khanna and/or Biggar. Khanna does not disclose administration of a beta-cyclodextrin "prior to vaginal birth" or "at a site of a surgical incision for a cesarean section birth" to reduce maternal to fetal transmission of HIV. Khanna discloses that the "mice were pretreated with 2.5 mg progestin [Depo-Provera]; 1 week later, three groups of three mice each were *inoculated* with 50 μ l of... β -CD" (page 207, col. 2, first paragraph). So, the claimed invention is distinguished from Khanna because the animals in Khanna received β -CD inoculations and not topical administration to the birth canal (intravaginally), and they were not pregnant as they were pre-treated with a Depo-Provera, a drug used to prevent pregnancy. Thus, one skilled in the art from reviewing Khanna would not be able to determine whether β -CD reduces of maternal to fetal transmission of any microorganism.

Biggar does not cure any deficiency of either the '717 patent or Khanna, because Biggar does not disclose that the beta-cyclodextrin can be administered "prior to vaginal birth" or "at a site of a surgical incision for a cesarean section birth". Biggar discloses antiseptic (0.25% chlorhexidine in sterile water) cleansing of the birth canal in women, however, women who were

excluded from the washes where those in “preterm labour without membrane rupture, known to have obstetric problems (including those undergoing elective caesarean sections), [or] admitted in second stage labour (page 1648, col. 1, 4th paragraph)”. Thus, the women excluded from Biggar’s study would not be excluded from using the claimed method, as discussed in more detail below, the claimed method can be used just prior to vaginal or cesarean birth.

For example, the instant application describes that the cholesterol-sequestering agents can be administered:

...to the birth canal of the pregnant individual *before* birth. For example, the composition can be administered to the birth canal *at least* 1, 2, 3, 4, 5, 6, 12, 24, 48, 72, or more hours before birth. In some examples, the composition is administered to the birth canal *less than* 72, 48, 24, 12, 6, 5, 4, 3, 2, or *1 hour before birth*. [emphasis added; page 3, lines 5-9 of the specification]

Hence, the above indicates that the claimed invention can be administered right up to the time of birth or delivery. Further, the claimed invention can be administered “either [in] a vaginal birth or [in] a cesarean section birth (page 9, lines 18-19 of the specification)”. Thus, the claimed invention is distinguished from the combination of the ‘717 patent, Khanna and Biggar because the claimed invention administers beta-cyclodextrin to a “pregnant individual”, “prior to a vaginal birth (claim 1)”, as well as “at a site of surgical incision for a caesarean section birth (claim 31)”. Therefore, the combination of the ‘717 patent, Khanna and Biggar do not teach or suggest all the claim limitations as required for a *prima facie* case of obviousness rejection.

Accordingly, withdrawal of rejection of claims 1-31 under 35 U.S.C. §103, is respectfully requested.

In the Application of:
Scheele and Hildreth
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Attorney Docket No. JHU1710-6

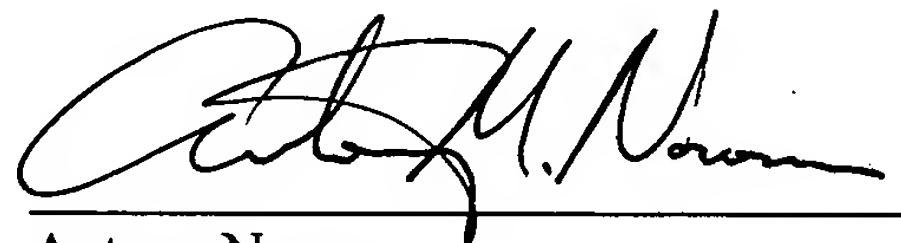
Conclusion

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

Check number 581962 in the amount of \$60.00 is enclosed as payment for the one-month Petition for Extension of Time fee and check numbers 581995 and 581968, both in the amount of \$65.00, for two Terminal Disclaimer fees. No other fee is deemed necessary with the filing of this paper. However if any fees are due, the Commissioner is hereby authorized to charge any fees, or make any credits, to Deposit Account No. 07-1896 referencing the above-identified attorney docket number. A copy of this Transmittal Sheet is enclosed.

Respectfully submitted,

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